



Food and Drug Administration
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January 8, 2015

OMEGA LABORATORIES, INC.
ROBERT BARD
MANAGING DIRECTOR
400 NORTH CLEVELAND
MOGADORE OH 44260

Re: K140671

Trade/Device Name: Omega Laboratories Hair Drug Screening Assay, (Opiates, Oxycodone and Hydrocodone)

Regulation Number: 21 CFR 862.3650

Regulation Name: Opiate test system

Regulatory Class: II

Product Code: DJG

Dated: January 5, 2015

Received: January 6, 2015

Dear Mr. Robert Bard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Stayce Beck -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

k140671

Device Name

Omega Laboratories Inc. Hair Drug Screening Assay (Opiates, Oxycodone and Hydrocodone)

Indications for Use (Describe)

The Omega Laboratories Hair Drug Screening Assay (Opiates, Oxycodone and Hydrocodone) is an in vitro diagnostic test that is intended for the qualitative detection of opiates (calibrated with morphine) and oxycodone and hydrocodone (calibrated with oxycodone) at or above 300 pg/mg in human head and body hair. To confirm a screen positive result, a more specific alternate chemical method, such as Gas Chromatography/Mass Spectrometry (GC/MS) operating in the selected ion monitoring (SIM) mode is the preferred method with deuterated internal standards. Professional judgment should be applied to any drug of abuse test result, particularly when presumptive positive results are obtained.

This test is intended exclusively for single laboratory use only and is not intended for sale to anyone.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

510(k) Number: K140671

Date of Summary: January 5, 2015

Applicant: William R. Corl
Chief Executive Officer
Omega Laboratories, Inc.
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Mogadore, OH 44260
Tel: 330-628-5748
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Correspondent:
Name: ROBERT J BARD, JD, CQE, RAC
Address: Omega Laboratories
400 North Cleveland, Mogadore, OH 44260
Phone Number: 248-573-5040
E-mail: rbard@reglaw.net

Product Name:
Trade Name: Omega Laboratories Inc. Hair Drug Screening Assay (Opiates, Oxycodone and Hydrocodone)
Common Name: Hair Drug Screening Assay Opiates
Regulation Number: CFR 862.3650 (ProCode DJG)

Classification Name: Opiate test system.

Classification Panel: 91 (Toxicology)

Predicate Device: Omega Hair Drug Screening Assay for Opiates, Oxycodone and Hydrocodone (k103161)

Indication for Use: The Omega Laboratories Hair Drug Screening Assay (Opiates, Oxycodone and Hydrocodone) is an in vitro diagnostic test that is intended for the qualitative detection of opiates (calibrated with morphine) and oxycodone and hydrocodone (calibrated with oxycodone) at or above 300 pg/mg in human head and body hair. To confirm a screen positive result, a more specific alternate chemical method, such as Gas Chromatography/Mass Spectrometry (GC/MS) operating in the selected ion monitoring (SIM) mode is the preferred method with deuterated internal standards. Professional judgment should be applied to any drug of abuse test result, particularly when presumptive positive results are obtained.

This test is intended exclusively for single laboratory use only and is not intended for sale to anyone.

Comparison: When used to qualitatively detect Opiates, Oxycodone and Hydrocodone in head and body hair specimens collected with the Omega Specimen Collection Device, the Omega assays yield results in substantial agreement with the predicate device (see Table 1 below).

Comparison Performance Data: All performance studies demonstrated that the Omega assay is in substantial agreement with the predicate products.

Results obtained from donor specimens showed that the qualitative results from the new assays are substantially equivalent to those obtained from the predicate devices.

Table 1: Comparison of Omega Hair Drug Screening Assay for Opiates, Oxycodone and Hydrocodone

Comparison Element - Similarities	Hair Drug Screening Assay for Opiates, Oxycodone and Hydrocodone. (Subject devices K140671)	Hair Drug Screening Assay Opiates, Oxycodone and Hydrocodone (Predicate device k103161)
Laboratory	Omega Laboratories, Inc.	Same.
Indication for/ Intended Use	The Omega Laboratories Hair Drug Screening Assay (Opiates, Oxycodone and Hydrocodone) is an in vitro diagnostic test that is intended for the qualitative detection of opiates (calibrated with morphine) and oxycodone and hydrocodone (calibrated with oxycodone) at or above 300 pg/mg in human head and body hair. To confirm a screen positive result, a more specific alternate chemical method, such as Gas Chromatography/Mass Spectrometry (GC/MS) operating in the selected ion monitoring (SIM) mode is the preferred method with deuterated internal standards. Professional judgment should be applied to any drug of abuse test result, particularly when presumptive positive results are obtained. This test is intended exclusively for single laboratory use only and is not intended for sale to anyone.	The Omega Laboratories Hair Drug Screening Assays are test systems that utilize ELISA assays for the qualitative detection of morphine and related opiates (calibrated with morphine) and oxycodone and hydrocodone (calibrated with oxycodone) at or above 300 pg/mg in head hair samples. The Omega Laboratories Hair Drug Screening Assay for Opiates, Oxycodone and Hydrocodone provide only preliminary analytical test results. A more specific alternate chemical method must be used in order to obtain a confirmed result. Gas Chromatograph – Mass Spectrometry operating in the selected ion monitoring (SIM) mode or GC/MS/MS in selected reaction mode (SRM) is the preferred method with deuterated internal standards.
Method of Measurement	Microplate reader. Read at 450 nm	Same.
Matrix	Head and body hair	Head hair
Cutoff concentration	300 pg Opiates, Oxycodone and Hydrocodone /mg hair	Same.
Assay Principal	ELISA	Same.

Table 1: Comparison of Omega Hair Drug Screening Assay for Opiates, Oxycodone and Hydrocodone

Comparison Element - Similarities	Hair Drug Screening Assay for Opiates, Oxycodone and Hydrocodone. (Subject devices K140671)	Hair Drug Screening Assay Opiates, Oxycodone and Hydrocodone (Predicate device k103161)
Extraction Method	Utilized acid-methanol vs. methanol alone to facilitate extraction of drug from hair. Proprietary and patent pending method of pulverizing hair vs. cutting the hair into small segments prior to acid-methanol extraction. This improved extraction times without loss of efficiency	Same.

Performance Studies

PRECISION :

Intra-assay precision studies were performed using 11 replicates of negative head hair samples spiked to the following concentrations of opiates, oxycodone, and hydrocodone: zero drug, -75%, -50%, -25% below the cutoff, and +25%, +50%, +75% and +100% above the cutoff. All samples were treated and analyzed in the same manner as donor hair samples and measured in one run. Head hair was used in this study.

Table 2: Intra-Assay Precision Studies (opiates, oxycodone and hydrocodone)

Drug	Concentration of Sample (pg/mg)	Number of Replicates	Results # Negative	Results # Positive
Opiates	0	11	11	0
Opiates	75	11	11	0
Opiates	150	11	11	0
Opiates	225	11	11	0
Opiates	375	11	0	11
Opiates	450	11	0	11
Opiates	525	11	0	11
Opiates	600	11	0	11
Oxycodone	0	11	11	0
Oxycodone	75	11	11	0
Oxycodone	150	11	11	0
Oxycodone	225	11	11	0
Oxycodone	375	11	0	11
Oxycodone	450	11	0	11
Oxycodone	525	11	0	11
Oxycodone	600	11	0	11

Table 2: Intra-Assay Precision Studies (opiates, oxycodone and hydrocodone)

Drug	Concentration of Sample (pg/mg)	Number of Replicates	Results # Negative	Results # Positive
Hydrocodone	0	10	10	0
Hydrocodone	75	10	10	0
Hydrocodone	150	10	10	0
Hydrocodone	225	10	9	1
Hydrocodone	375	10	0	10
Hydrocodone	450	10	0	10
Hydrocodone	525	10	0	10
Hydrocodone	600	10	0	10

Inter-assay precision studies were performed using negative hair samples spiked to the following concentrations of opiates, oxycodone and hydrocodone: zero drug, -75%, -50%, -25% below the cutoff, and +25%, +50%, +75% and +100% above the cutoff.

All samples were treated and analyzed in the same manner as donor hair samples, which is summarized in Section 9.0. Eleven replicates of these were prepared and analyzed over 20 non-consecutive days. The results of this study are summarized in the tables below and the raw data is attached.

Tables 15a through 15c summarize the result of the Opiates, Oxycodone and Hydrocodone Inter-Assay Precision testing of the Omega Laboratories Drug Screening in Hair Assays.

Table 3a: Inter-assay Opiates Precision Study Summary (non-normalized)

Drug	Conc. (pg/mg) (% of Cutoff)	Number Tested	Negative	Positive
Opiates	0 (Negative)	220	220	0
Opiates	75 (-75)	220	220	0
Opiates	150 (-50)	220	220	0
Opiates	225 (-25)	220	220	0
Opiates	375 (125)	220	0	220
Opiates	450 (150)	220	0	220
Opiates	525 (175)	220	0	220
Opiates	600 (200)	220	0	220

Table 3b: Inter-assay Oxycodone Precision Study Summary (non-normalized)

Drug	Conc. (pg/mg) (% of Cutoff)	Number Tested	Negative	Positive
Oxycodone	0 (Negative)	220	220	0
Oxycodone	75 (-75)	220	220	0
Oxycodone	150 (-50)	220	220	0
Oxycodone	225 (-25)	220	220	0

Drug	Conc. (pg/mg) (% of Cutoff)	Number Tested	Negative	Positive
Oxycodone	375 (125)	220	0	220
Oxycodone	450 (150)	220	0	220
Oxycodone	525 (175)	220	0	220
Oxycodone	600 (200)	220	0	220

Table 3c: Inter-assay Hydrocodone Precision Study Summary (non-normalized)

Drug	Conc. (pg/mg) % of Cutoff	Number Tested	Negative	Positive
Hydrocodone	0 (Negative)	100	100	0
Hydrocodone	75 (-75)	100	100	0
Hydrocodone	150 (-50)	100	100	0
Hydrocodone	225 (-25)	100	61	39
Hydrocodone	375 (125)	100	0	100
Hydrocodone	450 (150)	100	0	100
Hydrocodone	525 (175)	100	0	100
Hydrocodone	600 (200)	100	0	100

AGREEMENT STUDIES:

The method comparison was performed using two opiates studies by testing 226 head and body hair samples consisting of 176 head hair samples in Study 1 and 50 body hair samples in Study 3.

Agreement studies also included 530 head and body hair samples that were tested in three oxycodone and hydrocodone studies consisting of 240 head hair samples in Study 1, 240 head hairs samples in retrospective analysis Study 2 and 50 body hair samples in Study 3.

In the studies, each specimen was divided into two aliquots and one was used for screening and the other for GC/MS confirmation. Testing was performed on body and head hair samples from different ages, gender, ethnicities and hair color. The results were:

Opiates Agreement Studies (from Studies 1 and 3)

Table 3a: Opiates Equivalents Summary of Agreement Study Results (n=226) Head and Body

ELISA Test Result	Negative by GC/MS	Less than half the cutoff concentration by GC/MS	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (Greater than 50% above the cutoff concentration)
Positive	0	0	2	24	116
Negative	70	4	9	1	0

Table 3b: GC/MS Summary of Opiates Equivalents Discordant Results

Sample No.	Screening Cutoff (pg/mg)	ELISA Test Result (POS/NEG)	GC/MS Cutoff (pg/mg)	GC/MS Drug Result (pg/mg)
16	300	POS	300	HDC 268
150	300	POS	300	HDC 299
29	300	NEG	300	HDC 354

Oxycodone and Hydrocodone Agreement Studies (from Studies 1,2 and 3)

Table 4a: Oxycodone Summary of Agreement Study Results (n=483*)

ELISA Test Result	Negative by GC/MS	Less than half the cutoff concentration by GC/MS	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (Greater than 50% above the cutoff concentration)
Positive	0	0	6	94	221
Negative	140	6	14	2	0

*Of the 530 samples compared in the Oxy assays, 46 ELISA positive head hair samples were negative by GC/MS confirmation for oxycodone but positive for hydrocodone and one head hair test sample was lost during centrifugation reducing the number of test samples reported here to 483.

Table 4b: GC/MS Summary of Oxycodone Discordant Results

Sample No.	Screening Cutoff (pg/mg)	ELISA Test Result (POS/NEG)	GC/MS Cutoff (pg/mg)	GC/MS Drug Result (pg/mg)
835334	300	NEG	300	OXY 169 HDC 167
EXOP 39	300	POS	300	OXY 131 HDC 83
788840	300	POS	300	OXY 185 HDC 29
787180c	300	POS	300	OXY 229 HDC 68
789526	300	POS	300	OXY 240 HDC 49
872104	300	NEG	300	OXY 130 HDC 221

Table 4b: GC/MS Summary of Oxycodone Discordant Results

Sample No.	Screening Cutoff (pg/mg)	ELISA Test Result (POS/NEG)	GC/MS Cutoff (pg/mg)	GC/MS Drug Result (pg/mg)
854976	300	POS	300	OXY 255
800488	300	POS	300	OXY 298

Table 4c: Hydrocodone Summary of Agreement Study Results (n=500*)

ELISA Test Result	Negative by GC/MS	Less than half the cutoff concentration by GC/MS	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (Greater than 50% above the cutoff concentration)
Positive	0	0	8	110	201
Negative	142	8	25	6	0

*Of the 530 samples compared in the HDC assays, 27 ELISA positive head hair samples were negative by GC/MS confirmation for hydrocodone but positive for oxycodone, one head hair test sample was lost during centrifugation and 2 ELISA head hair positive samples were not able to be confirmed by GC/MS which reduced the number of test samples reported here to 500.

Table 4d: GC/MS Summary of Hydrocodone Discordant Results

Sample No.	Screening Cutoff (pg/mg)	ELISA Test Result (POS/NEG)	GC/MS Cutoff (pg/mg)	GC/MS Drug Result (pg/mg)
787832	300	NEG	300	HDC 403
89	300	NEG	300	HDC 313
65	300	NEG	300	HDC 334
835334	300	NEG	300	HDC 167 OXY 169
872104	300	NEG	300	HDC 221 OXY 130
835981a	300	NEG	300	HDC 347
788840	300	POS	300	HDC 29 OXY 185
789526	300	POS	300	HDC 49 OXY 240
787180c	300	POS	300	HDC 68 OXY 229

Table 4d: GC/MS Summary of Hydrocodone Discordant Results

Sample No.	Screening Cutoff (pg/mg)	ELISA Test Result (POS/NEG)	GC/MS Cutoff (pg/mg)	GC/MS Drug Result (pg/mg)
EXOP 39	300	POS	300	HDC 83 OXY 131
790194	300	POS	300	HDC 204
849237	300	POS	300	HDC 256
904316	300	POS	300	HDC 272
780598	300	POS	300	HDC 283

CROSSREACTIVITY:

The Cross-reactivity study was designed to evaluate the specificity of the Omega Laboratories, Inc. ELISA Screening Protocol and the possible effect of interfering compounds.

Table 5a: Cross-reactivity of Opiates ELISA with Structurally Similar Compounds:

Compound	Approximate Concentration of Compound (pg/mg) Equivalent to 300pg/mg Opiates Cutoff Control (n=3)	Percent Cross-reactivity (%)
Morphine	300	100.0
Heroin	200	150.0
Codeine	250	120.0
6-Acetylcodeine	275	109.1
Ethylmorphine	200	150.0
Dihydrocodeine	700	42.9
6-Monoacetylmorphine	200	150.0
Morphine-3-Beta-Glucuronide	700	42.9
Thebain	1250	24.0
Morphine-6-Beta-Glucuronide	600	50.0
Dihydromorphine	1500	20.0
Hydrocodone	1250	24.0
Hydromorphone	2000	15.0
Nalorphine	7000	4.3
Levorphanol	4000	7.5
Norcodeine	250000	0.1
Oxycodone	225000	0.1
Normorphine	175000	0.2
Diprenorphine	225000	0.1
Dextromethorphan	Not achieved at highest spike concentration.	

Table 5a: Cross-reactivity of Opiates ELISA with Structurally Similar Compounds:

Compound	Approximate Concentration of Compound (pg/mg) Equivalent to 300pg/mg Opiates Cutoff Control (n=3)	Percent Cross-reactivity (%)
	1000000 pg/mg	
Naltrexone	Not achieved at highest spike concentration. 1000000 pg/mg	
Norbuprenorphine	Not achieved at highest spike concentration. 1000000 pg/mg	
Buprenorphine	Not achieved at highest spike concentration. 1000000 pg/mg	
Oxymorphone	200000	0.2
Naltriben	Not achieved at highest spike concentration. 1000000 pg/mg	
Nalmefene	Not achieved at highest spike concentration. 1000000 pg/mg	
Apomorphine	Not achieved at highest spike concentration. 1000000 pg/mg	
Naloxone	Not achieved at highest spike concentration. 1000000 pg/mg	
Noroxymorphone	Not achieved at highest spike concentration. 1000000 pg/mg	
Noroxycodone	Not achieved at highest spike concentration. 1000000 pg/mg	
3-Methoxynaltrexone	Not achieved at highest spike concentration. 1000000 pg/mg	

Table 5b: Cross reactivity of ELISA Oxycodone with Structurally Similar Compounds

Compound	Approximate Concentration of Compound (pg/mg) Equivalent to 300pg/mg Oxycodone Cutoff Control (n=3)	Percent Cross-reactivity (%)
Hydrocodone	250	120
Oxycodone	300	100
Oxymorphone	1500	20
Dihydrocodeine	2500	12
6-Acetylcodeine	4000	7.5
Codeine	4500	6.7
Ethylmorphine	5000	6
Hydromorphone	6000	5
Heroin	15000	2
Dihydromorphine	15000	2
Levorphanol	15000	2

Table 5b: Cross reactivity of ELISA Oxycodone with Structurally Similar Compounds

Compound	Approximate Concentration of Compound (pg/mg) Equivalent to 300pg/mg Oxycodone Cutoff Control (n=3)	Percent Cross-reactivity (%)
6-Monoacetylmorphine	20000	1.5
Morphine	30000	1
Noroxycodone	30000	1
Thebaine	40000	0.75
Morphine-3-β-glucuronide	150000	0.2
Naloxone	250000	0.12
Norcodeine	400000	0.07
Morphine-6-β-glucuronide	Not achieved at highest spike concentration. 40000 pg/mg	
Norbuprenorphine	Not achieved at highest spike concentration. 40000 pg/mg	
Buprenorphine	Not achieved at highest spike concentration. 40000 pg/mg	
Noroxymorphone	Not achieved at highest spike concentration. 40000 pg/mg	
Nalorphine	Not achieved at highest spike concentration. 400000 pg/mg	
Normorphine	Not achieved at highest spike concentration. 400000 pg/mg	
Diprenorphine	Not achieved at highest spike concentration. 400000 pg/mg	
Dextromethorphan	Not achieved at highest spike concentration. 400000 pg/mg	
Naltrexone	Not achieved at highest spike concentration. 400000 pg/mg	
Naltriben	Not achieved at highest spike concentration. 400000 pg/mg	
Nalmefene	Not achieved at highest spike concentration. 400000 pg/mg	
Apomorphine	Not achieved at highest spike concentration. 400000 pg/mg	
3-Methoxy-naltrexone	Not achieved at highest spike concentration. 400000 pg/mg	

Effect of Interfering Compounds: A variety of structurally related and unrelated compounds were tested for interference at 10000ng/ml (400000pg/mg) in the Opiates ELISA and the Oxycodone ELISA assays. Negative hair extracts were spiked with morphine or oxycodone at -50% (125pg/mg), +125% (375pg/mg) and +150% (450pg/mg) of the Cutoff Concentration (300pg/mg). These were then additionally spiked with 10000ng/ml (400000pg/mg) of the structurally related and unrelated compounds unless otherwise noted. The absorbances were compared to the 300 pg/mg Cutoff control (CO). Only compounds that were structurally cross-reactive interfered in the assay. These structurally related compounds produced a

positive response due to sufficient cross-reactivity. No tested samples produced a negative result when expected to be positive. The analysis was performed in triplicate.

Table 5c: Interferences of Structurally Related and Unrelated Compounds on Opiates ELISA Assay

Compound	-50% CO (150pg/mg)	+125% CO (375pg/mg)	+150% CO (450pg/mg)
(-) 11-nor-9-carboxy-delta8-Tetrahydrocannabinol	NEG	POS	POS
(-) 11-nor-9-carboxy-delta9-Tetrahydrocannabinol	NEG	POS	POS
R (-) Amphetamine	NEG	POS	POS
(-) Cotinine	NEG	POS	POS
(-) Cotinine -N-oxide	NEG	POS	POS
(-) Isoproterenol	NEG	POS	POS
(-) Methamphetamine	NEG	POS	POS
(-) Nicotine	NEG	POS	POS
(-) Phenylephrine	NEG	POS	POS
(-)-Alpha-methadol	NEG	POS	POS
(+) Amphetamine	NEG	POS	POS
(+) Isoproterenol	NEG	POS	POS
(+) Methamphetamine	NEG	POS	POS
(+) Pseudoephedrine	NEG	POS	POS
(±) 11-nor-9-carboxy-delta9-Tetrahydrocannabinol	NEG	POS	POS
(±) 2,5-Dimethoxy- 4-bromoamphetamine	NEG	POS	POS
(±) Alphaprodine	NEG	POS	POS
(±) Ketamine	NEG	POS	POS
(±) MBDB	NEG	POS	POS
(±) MDA	NEG	POS	POS
(±) MDEA	NEG	POS	POS
(±) MDMA	NEG	POS	POS
(±) Metanephine	NEG	POS	POS
(±) Metoprolol	NEG	POS	POS
(±) Norcotinine	NEG	POS	POS
(±) Propanolol	NEG	POS	POS
(±) Trans-3'-Hydroxycotinine	NEG	POS	POS
11-Hydroxy-delta9-Tetrahydrocannabinol	NEG	POS	POS
19-Nortestosterone (Nandrolone)	NEG	POS	POS
1R,2S (-) Ephedrine	NEG	POS	POS
1S,2R (+) Ephedrine	NEG	POS	POS

Table 5c: Interferences of Structurally Related and Unrelated Compounds on Opiates ELISA Assay

Compound	-50% CO (150pg/mg)	+125% CO (375pg/mg)	+150% CO (450pg/mg)
2-Oxo-3-hydroxy-LSD	NEG	POS	POS
3-Methoxynaltrexone	NEG	POS	POS
3-Trans-Hydroxy-norcotinine	NEG	POS	POS
4-Acetoamidophenol	NEG	POS	POS
4-Hydroxy-Phencyclidine	NEG	POS	POS
5,5-Diphenylhydantoin	NEG	POS	POS
6-Acetyl-codeine	POS	POS	POS
6-Monoacetylmorphine	POS	POS	POS
7-Aminoclonazepam	NEG	POS	POS
7-Aminonitrazepam	NEG	POS	POS
Acebutolol	NEG	POS	POS
Acetophenetidin	NEG	POS	POS
Acetopromazine	NEG	POS	POS
Acetylsalicylic acid	NEG	POS	POS
Alfentanil	NEG	POS	POS
Alpha-Ergocryptine	NEG	POS	POS
Alprazolam	NEG	POS	POS
7-Aminoflunitrazepam	NEG	POS	POS
Aminorex	NEG	POS	POS
Amitriptyline	NEG	POS	POS
Amobarbital	NEG	POS	POS
Amoxicillin	NEG	POS	POS
Anhydroecgonine	NEG	POS	POS
Anileridine	NEG	POS	POS
Apomorphine	NEG	POS	POS
Atenolol	NEG	POS	POS
Azaperone	NEG	POS	POS
Benzoylecgonine	NEG	POS	POS
Benzoylecgonine isopropyl ester	NEG	POS	POS
Betamethasone	NEG	POS	POS
Boldenone	NEG	POS	POS
Bumetanide	NEG	POS	POS
Bupivacaine	NEG	POS	POS
Buprenorphine	POS	POS	POS

Table 5c: Interferences of Structurally Related and Unrelated Compounds on Opiates ELISA Assay

Compound	-50% CO (150pg/mg)	+125% CO (375pg/mg)	+150% CO (450pg/mg)
Buprenorphine-glucuronide (2500ng/ml)	NEG	POS	POS
Buspirone	NEG	POS	POS
Butabarbital	NEG	POS	POS
Butalbital	NEG	POS	POS
Caffeine	NEG	POS	POS
Cannabidiol	NEG	POS	POS
Cannabinol	NEG	POS	POS
Carbamazepine	NEG	POS	POS
Carisoprodol	NEG	POS	POS
Chlordiazepoxide	NEG	POS	POS
Chlorpromazine	NEG	POS	POS
Cimeterol	NEG	POS	POS
Clenbuterol	NEG	POS	POS
Clomipramine	NEG	POS	POS
Clonazepam	NEG	POS	POS
Clonidine	NEG	POS	POS
Clozapine	NEG	POS	POS
Cocaethylene	NEG	POS	POS
Cocaine	NEG	POS	POS
Codeine	POS	POS	POS
Corticosterone	NEG	POS	POS
Cortisone	NEG	POS	POS
Cotinine-N-beta-D-Glucuronide	NEG	POS	POS
Cyclobenzaprine	NEG	POS	POS
d,l-N-Desmethylenlafaxine	NEG	POS	POS
Delta8-Tetrahydrocannabinol	NEG	POS	POS
Delta9-Tetrahydrocannabinol	NEG	POS	POS
Deoxycorticosterone	NEG	POS	POS
Desalkylflurazepam	NEG	POS	POS
Desipramine	NEG	POS	POS
Desmethyldoxepin (cis/trans)	NEG	POS	POS
Despropionyl-fentanyl	NEG	POS	POS
Dexamethasone	NEG	POS	POS

Table 5c: Interferences of Structurally Related and Unrelated Compounds on Opiates ELISA Assay

Compound	-50% CO (150pg/mg)	+125% CO (375pg/mg)	+150% CO (450pg/mg)
Dextromethorphan	NEG	POS	POS
Diazepam	NEG	POS	POS
Dibucaine	NEG	POS	POS
Dihydrocodeine	POS	POS	POS
Dihydroergotamine	NEG	POS	POS
Dihydromorphine	POS	POS	POS
Diphenhydramine	NEG	POS	POS
Diphenoxylate	NEG	POS	POS
Diprenorphine	POS	POS	POS
Dothiepin (cis/trans)	NEG	POS	POS
Doxepin	NEG	POS	POS
Doxylamine	NEG	POS	POS
Droperidol	NEG	POS	POS
Ecgonine	NEG	POS	POS
Ecgonine methyl ester	NEG	POS	POS
EDDP	NEG	POS	POS
Effexor (Venlafaxine)	NEG	POS	POS
EMDP	NEG	POS	POS
Ergonovine	NEG	POS	POS
Erythromycin	NEG	POS	POS
Estazolam	NEG	POS	POS
Ethacrynic acid	NEG	POS	POS
Ethopropazine	NEG	POS	POS
Ethylmorphine	POS	POS	POS
Fenfluramine	NEG	POS	POS
Fentanyl	NEG	POS	POS
Flumethasone	NEG	POS	POS
Flunitrazepam	NEG	POS	POS
Fluphenazine	NEG	POS	POS
Flurazepam	NEG	POS	POS
Furosemide	NEG	POS	POS
Gentamicin	NEG	POS	POS
Gluthimide	NEG	POS	POS
Haloperidol	NEG	POS	POS

Table 5c: Interferences of Structurally Related and Unrelated Compounds on Opiates ELISA Assay

Compound	-50% CO (150pg/mg)	+125% CO (375pg/mg)	+150% CO (450pg/mg)
Heroin	POS	POS	POS
Hexobarbital	NEG	POS	POS
HMMA	NEG	POS	POS
Hydrochlorothiazide	NEG	POS	POS
Hydrocodone	POS	POS	POS
Hydrocortisone	NEG	POS	POS
Hydromorphone	POS	POS	POS
(±) 4-Hydroxyephedrine	NEG	POS	POS
Hydroxymethamphetamine	NEG	POS	POS
Ibogaine	NEG	POS	POS
Ibuprofen	NEG	POS	POS
Imipramine	NEG	POS	POS
Ketoprofen	NEG	POS	POS
LAAM	NEG	POS	POS
Labetalol	NEG	POS	POS
Levorphanol	POS	POS	POS
L-Hyoscyamine	NEG	POS	POS
Lidocaine	NEG	POS	POS
Lorazepam	NEG	POS	POS
LSD	NEG	POS	POS
Lysergic acid	NEG	POS	POS
Lysergol	NEG	POS	POS
Maprotiline	NEG	POS	POS
Meperidine	NEG	POS	POS
Mephentermine	NEG	POS	POS
Mepivacaine	NEG	POS	POS
Metaphit	NEG	POS	POS
Metaproterenol	NEG	POS	POS
Metaraminol	NEG	POS	POS
Methadone	NEG	POS	POS
Methohexital	NEG	POS	POS
Methoxyphenamine	NEG	POS	POS
Methylegonovine	NEG	POS	POS
Methylphenidate	NEG	POS	POS

Table 5c: Interferences of Structurally Related and Unrelated Compounds on Opiates ELISA Assay

Compound	-50% CO (150pg/mg)	+125% CO (375pg/mg)	+150% CO (450pg/mg)
m-Hydroxybenzoylecgonine	NEG	POS	POS
Mianserin	NEG	POS	POS
Midazolam	NEG	POS	POS
Monensin	NEG	POS	POS
Morphine	POS	POS	POS
Morphine-3-betaglucuronide	POS	POS	POS
Morphine-6-betaglucuronide	POS	POS	POS
Nadolol	NEG	POS	POS
Nalmefene	NEG	POS	POS
Nalorphine	POS	POS	POS
Naloxone-3-beta-D-glucuronide	NEG	POS	POS
Naltrexone	NEG	POS	POS
Naltriben	NEG	POS	POS
Naproxen	NEG	POS	POS
N-Desmethyldclomipramine	NEG	POS	POS
N-Desmethyflunitrazepam	NEG	POS	POS
N-Desmethyiltramadol	NEG	POS	POS
N-Desmethyiltrimipramine	NEG	POS	POS
Neomycin	NEG	POS	POS
Nitrazepam	NEG	POS	POS
Norbenzoylecgonine	NEG	POS	POS
Norbuprenorphine	NEG	POS	POS
Norcocaethylene	NEG	POS	POS
Norcocaine	NEG	POS	POS
Norcodeine	POS	POS	POS
Nordiazepam	NEG	POS	POS
Norfentanyl	NEG	POS	POS
Nor-LAAM	NEG	POS	POS
Nor-LSD/Nor-ISO-LSD	NEG	POS	POS
Normeperidine	NEG	POS	POS
Normeperidinic acid	NEG	POS	POS
Normorphine	POS	POS	POS
Noroxycodone	NEG	POS	POS
Noroxymorphone	POS	POS	POS

Table 5c: Interferences of Structurally Related and Unrelated Compounds on Opiates ELISA Assay

Compound	-50% CO (150pg/mg)	+125% CO (375pg/mg)	+150% CO (450pg/mg)
Norpropoxyphene	NEG	POS	POS
Nortriptyline	NEG	POS	POS
Noscapine	NEG	POS	POS
O-Desmethyiltramadol	NEG	POS	POS
Oxazepam	NEG	POS	POS
Oxprenolol	NEG	POS	POS
Oxycodone	POS	POS	POS
Oxymorphone	POS	POS	POS
p-Acetamidophenyl-beta-D-glucuronide	NEG	POS	POS
Papaverine	NEG	POS	POS
Pemoline	NEG	POS	POS
Penicillin G	NEG	POS	POS
Pentazocine	NEG	POS	POS
Pentobarbital	NEG	POS	POS
Perphenazine	NEG	POS	POS
Phendimetrazine	NEG	POS	POS
Phenelzine	NEG	POS	POS
Phenobarbital	NEG	POS	POS
Phenothiazine	NEG	POS	POS
Phentermine	NEG	POS	POS
Phenylbutazone	NEG	POS	POS
Phenylethylamine	NEG	POS	POS
Phenylpropanolamine	NEG	POS	POS
PMA	NEG	POS	POS
PMMA	NEG	POS	POS
Prednisolone	NEG	POS	POS
Prilocaine	NEG	POS	POS
Prochlorperazine	NEG	POS	POS
Progesterone	NEG	POS	POS
Promazine	NEG	POS	POS
Promethazine	NEG	POS	POS
Propiomazine	NEG	POS	POS
Propionylpromazine	NEG	POS	POS
Propoxyphene	NEG	POS	POS

Table 5c: Interferences of Structurally Related and Unrelated Compounds on Opiates ELISA Assay

Compound	-50% CO (150pg/mg)	+125% CO (375pg/mg)	+150% CO (450pg/mg)
Protriptyline	NEG	POS	POS
Quinidine	NEG	POS	POS
R (+) Methcathinone	NEG	POS	POS
R (-) Epinephrine	NEG	POS	POS
R (+) Cathinone	NEG	POS	POS
Salbutamol	NEG	POS	POS
Secobarbital	NEG	POS	POS
Sertraline	NEG	POS	POS
Stanazolol	NEG	POS	POS
Streptomycin	NEG	POS	POS
Sulfadimethoxine	NEG	POS	POS
Sulfamethazine	NEG	POS	POS
Sulfathiazole	NEG	POS	POS
Temazepam	NEG	POS	POS
Terbutaline	NEG	POS	POS
Tetracycline	NEG	POS	POS
Thebaine	POS	POS	POS
Theophylline	NEG	POS	POS
Thioridazine	NEG	POS	POS
Tramadol	NEG	POS	POS
Triamcinolone	NEG	POS	POS
Triazolam	NEG	POS	POS
Trifluoperazine	NEG	POS	POS
Trifluopromazine	NEG	POS	POS
Trimeprazine	NEG	POS	POS
Trimipramine	NEG	POS	POS
Tylosin	NEG	POS	POS
Tyramine	NEG	POS	POS
Yohimbic acid	NEG	POS	POS
Yohimbine	NEG	POS	POS
Zolpidem	NEG	POS	POS
Zopiclone	NEG	POS	POS
Phencyclidine	NEG	POS	POS
R,R (-)-Pseudoephedrine	NEG	POS	POS

Table 5c: Interferences of Structurally Related and Unrelated Compounds on Opiates ELISA Assay

Compound	-50% CO (150pg/mg)	+125% CO (375pg/mg)	+150% CO (450pg/mg)
Phencyclidine Morpholine	NEG	POS	POS

Table 5d: Interferences of Structurally Related and Unrelated Compounds on Oxycodone ELISA Sys

Compound	-50% CO (150pg/mg)	+125% CO (375pg/mg)	+150% CO (450pg/mg)
(-) 11-nor-9-carboxy-delta8-Tetrahydrocannabinol	NEG	POS	POS
(-) 11-nor-9-carboxy-delta9-Tetrahydrocannabinol	NEG	POS	POS
R (-) Amphetamine	NEG	POS	POS
(-) Cotinine	NEG	POS	POS
(-) Cotinine -N-oxide	NEG	POS	POS
(-) Isoproterenol	NEG	POS	POS
(-) Methamphetamine	NEG	POS	POS
(-) Nicotine	NEG	POS	POS
(-) Phenylephrine	NEG	POS	POS
(-)-Alpha-methadol	NEG	POS	POS
(+) Amphetamine	NEG	POS	POS
(+) Isoproterenol	NEG	POS	POS
(+) Methamphetamine	NEG	POS	POS
(+) Pseudoephedrine	NEG	POS	POS
(±) 11-nor-9-carboxy-delta9-Tetrahydrocannabinol	NEG	POS	POS
(±) 2,5-Dimethoxy- 4-bromoamphetamine	NEG	POS	POS
(±) Alphaprodine	NEG	POS	POS
(±) Ketamine	NEG	POS	POS
(±) MBDB	NEG	POS	POS
(±) MDA	NEG	POS	POS
(±) MDEA	NEG	POS	POS
(±) MDMA	NEG	POS	POS
(±) Metanephrene	NEG	POS	POS
(±) Metoprolol	NEG	POS	POS
(±) Norcotinine	NEG	POS	POS
(±) Propanolol	NEG	POS	POS

Table 5d: Interferences of Structurally Related and Unrelated Compounds on Oxycodone ELISA Sys

Compound	-50% CO (150pg/mg)	+125% CO (375pg/mg)	+150% CO (450pg/mg)
(±) Trans-3'-Hydroxycotinine	NEG	POS	POS
11-Hydroxy-delta9-Tetrahydrocannabinol	NEG	POS	POS
19-Nortestosterone (Nandrolone)	NEG	POS	POS
1R,2S (-) Ephedrine	NEG	POS	POS
1S,2R (+) Ephedrine	NEG	POS	POS
2-Oxo-3-hydroxy-LSD	NEG	POS	POS
3-Methoxynaltrexone	POS	POS	POS
3-Trans-Hydroxy-norcotinine	NEG	POS	POS
4-Acetoamidophenol	NEG	POS	POS
4-Hydroxy-Phencyclidine	NEG	POS	POS
5,5-Diphenylhydantoin	NEG	POS	POS
6-Acetyl-codeine	POS	POS	POS
6-Monoacetylmorphine	POS	POS	POS
7-Aminoclonazepam	NEG	POS	POS
7-Aminonitrazepam	NEG	POS	POS
Acebutolol	NEG	POS	POS
Acetophenetidin	NEG	POS	POS
Acetopromazine	NEG	POS	POS
Acetylsalicylic acid	NEG	POS	POS
Alfentanil	NEG	POS	POS
Alpha-Ergocryptine	NEG	POS	POS
Alprazolam	NEG	POS	POS
7-Aminoflunitrazepam	NEG	POS	POS
Aminorex	NEG	POS	POS
Amitriptyline	NEG	POS	POS
Amobarbital	NEG	POS	POS
Amoxicillin	NEG	POS	POS
Anhydroecgonine	NEG	POS	POS
Anileridine	NEG	POS	POS
Apomorphine	NEG	POS	POS
Atenolol	NEG	POS	POS
Atropine	NEG	POS	POS
Azaperone	NEG	POS	POS
Benzoylecgonine	NEG	POS	POS

Table 5d: Interferences of Structurally Related and Unrelated Compounds on Oxycodone ELISA Sys

Compound	-50% CO (150pg/mg)	+125% CO (375pg/mg)	+150% CO (450pg/mg)
Benzoylcegonine isopropyl ester	NEG	POS	POS
Betamethasone	NEG	POS	POS
Boldenone	NEG	POS	POS
Bumetanide	NEG	POS	POS
Bupivacaine	NEG	POS	POS
Buprenorphine	NEG	POS	POS
Buspirone	NEG	POS	POS
Butabarbital	NEG	POS	POS
Butalbital	NEG	POS	POS
Caffeine	NEG	POS	POS
Cannabidiol	NEG	POS	POS
Cannabinol	NEG	POS	POS
Carbamazepine	NEG	POS	POS
Carisoprodol	NEG	POS	POS
Chlordiazepoxide	NEG	POS	POS
Chlorpromazine	NEG	POS	POS
Cimeterol	NEG	POS	POS
Clenbuterol	NEG	POS	POS
Clomipramine	NEG	POS	POS
Clonazepam	NEG	POS	POS
Clonidine	NEG	POS	POS
Clozapine	NEG	POS	POS
Cocaethylene	NEG	POS	POS
Cocaine	NEG	POS	POS
Codeine	POS	POS	POS
Corticosterone	NEG	POS	POS
Cortisone	NEG	POS	POS
Cotinine-N-beta-D-Glucuronide	NEG	POS	POS
Cyclobenzaprine	NEG	POS	POS
d,l-N-Desmethylvenlafaxine	NEG	POS	POS
Delta8-Tetrahydrocannabinol	NEG	POS	POS
Delta9-Tetrahydrocannabinol	NEG	POS	POS
Deoxycorticosterone	NEG	POS	POS
Desalkylflurazepam	NEG	POS	POS

Table 5d: Interferences of Structurally Related and Unrelated Compounds on Oxycodone ELISA Sys

Compound	-50% CO (150pg/mg)	+125% CO (375pg/mg)	+150% CO (450pg/mg)
Desipramine	NEG	POS	POS
Desmethyldoxepin (cis/trans)	NEG	POS	POS
Despropionyl-fentanyl	NEG	POS	POS
Dexamethasone	NEG	POS	POS
Dextromethorphan	NEG	POS	POS
Diazepam	NEG	POS	POS
Dibucaine	NEG	POS	POS
Dihydrocodeine	POS	POS	POS
Dihydroergotamine	NEG	POS	POS
Dihydromorphine	POS	POS	POS
Diphenhydramine	NEG	POS	POS
Diphenoxylate	NEG	POS	POS
Diprenorphine	NEG	POS	POS
Dothiepin (cis/trans)	NEG	POS	POS
Doxepin	NEG	POS	POS
Doxylamine	NEG	POS	POS
Droperidol	NEG	POS	POS
Ecgonine	NEG	POS	POS
Ecgonine methyl ester	NEG	POS	POS
EDDP	NEG	POS	POS
Effexor (Venlafaxine)	NEG	POS	POS
EMDP	NEG	POS	POS
Ergonovine	NEG	POS	POS
Erythromycin	NEG	POS	POS
Estazolam	NEG	POS	POS
Ethacrynic acid	NEG	POS	POS
Ethopropazine	NEG	POS	POS
Ethylmorphine	POS	POS	POS
Fenfluramine	NEG	POS	POS
Fentanyl	NEG	POS	POS
Flumethasone	NEG	POS	POS
Flunitrazepam	NEG	POS	POS
Fluphenazine	NEG	POS	POS
Flurazepam	NEG	POS	POS

Table 5d: Interferences of Structurally Related and Unrelated Compounds on Oxycodone ELISA Sys

Compound	-50% CO (150pg/mg)	+125% CO (375pg/mg)	+150% CO (450pg/mg)
Furosemide	NEG	POS	POS
Gentamicin	NEG	POS	POS
Gluthimide	NEG	POS	POS
Haloperidol	NEG	POS	POS
Heroin	POS	POS	POS
Hexobarbital	NEG	POS	POS
HMMA	NEG	POS	POS
Hydrochlorothiazide	NEG	POS	POS
Hydrocodone	POS	POS	POS
Hydrocortisone	NEG	POS	POS
Hydromorphone	POS	POS	POS
(±) 4-Hydroxyephedrine	NEG	POS	POS
Hydroxymethamphetamine	NEG	POS	POS
Ibogaine	NEG	POS	POS
Ibuprofen	NEG	POS	POS
Imipramine	NEG	POS	POS
Ketoprofen	NEG	POS	POS
LAAM	NEG	POS	POS
Labetalol	NEG	POS	POS
LAMPA (1000ng/ml)	NEG	POS	POS
Levorphanol	POS	POS	POS
L-Hyoscyamine	NEG	POS	POS
Lidocaine	NEG	POS	POS
Lorazepam	NEG	POS	POS
LSD	NEG	POS	POS
Lysergic acid	NEG	POS	POS
Lysergol	NEG	POS	POS
Maprotiline	NEG	POS	POS
Meperidine	NEG	POS	POS
Mephentermine	NEG	POS	POS
Mepivacaine	NEG	POS	POS
Metaphit	NEG	POS	POS
Metaproterenol	NEG	POS	POS
Metaraminol	NEG	POS	POS

Table 5d: Interferences of Structurally Related and Unrelated Compounds on Oxycodone ELISA Sys

Compound	-50% CO (150pg/mg)	+125% CO (375pg/mg)	+150% CO (450pg/mg)
Methadone	NEG	POS	POS
Methohexital	NEG	POS	POS
Methoxyphenamine	NEG	POS	POS
Methylergonovine	NEG	POS	POS
Methylphenidate	NEG	POS	POS
m-Hydroxybenzoylecgonine	NEG	POS	POS
Mianserin	NEG	POS	POS
Midazolam	NEG	POS	POS
Monensin	NEG	POS	POS
Morphine	POS	POS	POS
Morphine-3-beta-glucuronide	POS	POS	POS
Morphine-6-beta-glucuronide	POS	POS	POS
Nadolol	NEG	POS	POS
Nalmefene	POS	POS	POS
Nalorphine	POS	POS	POS
Naloxone-3-beta-D-glucuronide	POS	POS	POS
Naltrexone	POS	POS	POS
Naltriben	POS	POS	POS
Naproxen	NEG	POS	POS
N-Desmethyldimipramine	NEG	POS	POS
N-Desmethylnitrazepam	NEG	POS	POS
N-Desmethyltramadol	NEG	POS	POS
N-Desmethyltrimipramine	NEG	POS	POS
Neomycin	NEG	POS	POS
Nitrazepam	NEG	POS	POS
Norbenzoylecgonine	NEG	POS	POS
Norbuprenorphine	NEG	POS	POS
Norcocaine	NEG	POS	POS
Norcodeine	POS	POS	POS
Nordiazepam	NEG	POS	POS
Norfentanyl	NEG	POS	POS
Nor-LAAM	NEG	POS	POS
Nor-LSD/Nor-ISO-LSD	NEG	POS	POS

Table 5d: Interferences of Structurally Related and Unrelated Compounds on Oxycodone ELISA Sys

Compound	-50% CO (150pg/mg)	+125% CO (375pg/mg)	+150% CO (450pg/mg)
Normeperidine	NEG	POS	POS
Normeperidinic acid	NEG	POS	POS
Normorphine	POS	POS	POS
Noroxycodone	POS	POS	POS
Noroxymorphone	POS	POS	POS
Norpropoxyphene	NEG	POS	POS
Nortriptyline	NEG	POS	POS
Noscapine	NEG	POS	POS
O-Desmethyltramadol	NEG	POS	POS
Oxazepam	NEG	POS	POS
Oxprenolol	NEG	POS	POS
Oxycodone	POS	POS	POS
Oxymorphone	POS	POS	POS
p-Acetamidophenyl-beta-D-glucuronide	NEG	POS	POS
Papaverine	NEG	POS	POS
Pemoline	NEG	POS	POS
Penicillin G	NEG	POS	POS
Pentazocine	NEG	POS	POS
Pentobarbital	NEG	POS	POS
Perphenazine	NEG	POS	POS
Phendimetrazine	NEG	POS	POS
Phenelzine	NEG	POS	POS
Phenobarbital	NEG	POS	POS
Phenothiazine	NEG	POS	POS
Phentermine	NEG	POS	POS
Phenylbutazone	NEG	POS	POS
Phenylethylamine	NEG	POS	POS
Phenylpropanolamine	NEG	POS	POS
Phencyclidine	NEG	POS	POS
R,R (-)-Pseudoephedrine	NEG	POS	POS
Phencyclidine Morpholine	NEG	POS	POS
PMA	NEG	POS	POS
PMMA	NEG	POS	POS
Prednisolone	NEG	POS	POS

Table 5d: Interferences of Structurally Related and Unrelated Compounds on Oxycodone ELISA Sys

Compound	-50% CO (150pg/mg)	+125% CO (375pg/mg)	+150% CO (450pg/mg)
Prilocaine	NEG	POS	POS
Prochlorperazine	NEG	POS	POS
Progesterone	NEG	POS	POS
Promazine	NEG	POS	POS
Promethazine	NEG	POS	POS
Propiomazine	NEG	POS	POS
Propionylpromazine	NEG	POS	POS
Propoxyphene	NEG	POS	POS
Protriptyline	NEG	POS	POS
Quinidine	NEG	POS	POS
R (+) Methcathinone	NEG	POS	POS
R (-) Epinephrine	NEG	POS	POS
R (+) Cathinone	NEG	POS	POS
Salbutamol	NEG	POS	POS
Secobarbital	NEG	POS	POS
Sertraline	NEG	POS	POS
Stanazolol	NEG	POS	POS
Streptomycin	NEG	POS	POS
Sulfadimethoxine	NEG	POS	POS
Sulfamethazine	NEG	POS	POS
Sulfathiazole	NEG	POS	POS
Temazepam	NEG	POS	POS
Terbutaline	NEG	POS	POS
Tetracycline	NEG	POS	POS
Thebaine	POS	POS	POS
Theophylline	NEG	POS	POS
Thioridazine	NEG	POS	POS
Tramadol	NEG	POS	POS
Triamcinolone	NEG	POS	POS
Triazolam	NEG	POS	POS
Trifluoperazine	NEG	POS	POS
Trifluopromazine	NEG	POS	POS
Trimeprazine	NEG	POS	POS
Trimipramine	NEG	POS	POS

Table 5d: Interferences of Structurally Related and Unrelated Compounds on Oxycodone ELISA Sys

Compound	-50% CO (150pg/mg)	+125% CO (375pg/mg)	+150% CO (450pg/mg)
Tylosin	NEG	POS	POS
Tyramine	NEG	POS	POS
Yohimbic acid	NEG	POS	POS
Yohimbine	NEG	POS	POS
Zolpidem	NEG	POS	POS
Zopiclone	NEG	POS	POS

This study demonstrated that the presence of the structurally similar compounds Buprenorphine, Noroxymorphone, 3-Methoxynaltrexone, Morphine-6-beta-glucuronide, Nalmefene, Nalorphine, Naloxone-3-beta-D-glucuronide, Naltrexone, Naltriben, and Noroxymorphone, may contribute to an Opiate or Oxycodone positive ELISA result when utilizing this protocol.

To better understand the observed cross-reactivity of the above identified compounds, the concentration ranges were extended to generate additional cross-reactivity (CR) data. With the extremely high concentrations, some cross-reactivity was now observable in all except for Nalmefene, Naloxone-3-beta-D-glucuronide and Naltriben.

The interference tests were also rerun at -50% of cutoffs. There was good correlation with the previous dataset. One interference test produced a different outcome. Specifically, Noroxymorphone in opiates assay. The calculated equivalents based on the CR curve resulted in a calculated equivalent concentration close to the assay cutoff.

5e: Cross reactivity of Opiates ELISA with Structurally Similar Compounds

Compound	Concentration of Compound (pg/mg) Equivalent to 300 pg/mg Opiates Cutoff Control	Percent Cross- Reactivity (%)
Morphine-6-β-D-glucuronide	800	37.5
Nalorphine	8500	3.5
Buprenorphine	600000	0.050
3-Methoxynaltrexone	900000	0.033
Naltrexone	3000000	0.010
Noroxymorphone	4000000	0.008
Nalmefene	*	0.00
Naloxone-3-β-D-glucuronide	*	0.00
Naltriben	*	0.00

* Unable to generate an assay absorbance equivalent to 300pg/mg Opiates cutoff. Highest concentration tested was 4,000,000pg/mg.

Table 5f: Interferences of Structurally Related and Unrelated Compounds on Opiates ELISA Assay All results at the - 50% of cutoff

Compounds	ELISA Assay Results	Opiates equivalents (pg/mg)
Morphine 6-β-D-glucuronide	POS	150300
Nalorphine	POS	14300
Buprenorphine	POS	500
3-Methoxynaltrexone	NEG	432
Naltrexone	NEG	340
Noroxymorphone	NEG	332
Nalmefene	NEG	332
Naloxone 3-β-D-glucuronide	NEG	332
Naltriben	NEG	332

Table 5g: Cross Reactivity of Omega Laboratories, Inc. Oxycodone ELISA with Structurally Similar Compounds

Compound	Concentration of Compound (pg/mg) Equivalent to 300 pg/mg Oxycodone Cutoff Control	Percent Cross-Reactivity (%)
Morphine-6-β-D-glucuronide	31000	0.97
Nalorphine	300000	0.10
Buprenorphine	*	0.00
3-Methoxynaltrexone	380000	0.08
Naltrexone	50000	0.60
Noroxymorphone	58000	0.52
Nalmefene	300000	0.10
Naloxone-3-β-D-glucuronide	680000	0.04
Naltriben	300000	0.10

* Unable to generate an assay absorbance equivalent to 300pg/mg Oxycodone cutoff. Highest concentration tested was 4,000,000pg/mg

Table 5h: Interferences of Structurally Related and Unrelated Compounds on Oxycodone ELISA Assay All results at the -50% of cutoff

Compound	ELISA Assay Results	Oxycodone equivalents (pg/mg)
Morphine 6-β-D-glucuronide	POS	4,180
Nalorphine	POS	700
Buprenorphine	NEG	340
3-Methoxynaltrexone	POS	620

Table 5h: Interferences of Structurally Related and Unrelated Compounds on Oxycodone ELISA Assay All results at the -50% of cutoff

Compound	ELISA Assay Results	Oxycodone equivalents (pg/mg)
Naltrexone	POS	2,700
Noroxymorphone	POS	2,380
Nalmefene	POS	700
Naloxone 3-β-D-glucuronide	POS	460
Naltriben	POS	340

None of the other compounds studied demonstrated any interference with the protocol.

CALIBRATOR AND CONTROL:

The Omega Laboratories, Inc. ELISA Opiates and Oxycodone Screening Protocols utilize in-house prepared calibrators and control solutions. The study successfully demonstrated the validation and stability of these solutions and the traceability to NIST standards.

The data demonstrating the stability of morphine and oxycodone in methanol for a period of one year when stored refrigerated in an amber bottle was provide as part of k103161. The quantitative values of 271 and 291 pg/mg for morphine and oxycodone, respectively, after a one year period is within 10% of the target value of 300 pg/mg. The study validated the one 1 year expiration date for the Calibrator Stock Solution.

STABILITY:

Hair samples were taken from the head were packaged (stored) in the Omega Collection Kit (The Hair Collection Kit consists of a poly transport bag, a small piece of foil, a small specimen pouch (envelope). The Collection Kit, containing the hair sample was previously confirmed positive then stored for an average of 3.1 years for opiate samples and stored for approximately 2 years for oxycodone and hydrocodone samples.

Fifty-four samples varying in ethnic origin, hair color and curvature were tested.

Table 6:Storage Stability Study Data Summary Ranges

Study Observation	Morphine	Codeine	6-AM	Oxycodone	Hydrocodone
Range in concentration pg/mg hair (Before)	520 - 1690	480 - 1150	600 - 2140	157 - 5174	196 - 2524
Range in concentration pg/mg hair (After)	530 - 1588	539 - 1132	636 - 1987	156 - 4638	207 - 2359
Mean Change	1%	7%	4%	-4%	-5%
% Max and Min Decrease	--20% and -3%	--2%	-8% and -7%	-16% and -1%	-23% and -1%

Table 6: Storage Stability Study Data Summary Ranges

Study Observation	Morphine	Codeine	6-AM	Oxycodone	Hydrocodone
% Max and Min Increase	35% and 1%	18% and 1%	16% and 1%	15% and 3%	6% and 5%
Number that increased in concentration	5	8	5	4	3
Number that decreased in concentration	7	2	2	8	10

Based on the data presented, opiates are stable in hair for 3 years and oxycodone and hydrocodone are stable for 2 year.

SHIPPING:

260 head hair samples were used in the shipping study; 155 samples previously confirmed positive, 100 previously screened negative samples and 5 samples that were confirmed below the 300 pg/mg cutoff. Each box contained a variety of hair color and curvature.

The minimum and maximum shipping temperature and humidity ranges are shown in the tables for the Negative samples and for the Positive samples below. Negative samples were shipped separate from the Positive samples.

Table 7a: Negative Samples Shipping Temperatures and Humidity Ranges Negative Samples

DataLogger ID	Shipped to Location Then Returned to Omega Laboratories	Min Temp (°C)	Max Temp (°C)	Min Humidity (%RH)	Max Humidity (%RH)
7310005629	1. Portland, Maine	-12.7	44.4	10.8	100
7310005644	2. Anchorage, Alaska	-9.4	44.9	8.1	96.1
7310005628	3. Naples, Florida	-10.8	43.3	4.4	100
7310005627	4. Tempe Arizona	-12.2	42.9	8.9	73.5

Table 7b: Positive Samples Shipping Temperatures and Humidity Ranges Positive Samples

DataLogger ID	Shipped to Location Then Returned to Omega Laboratories	Min Temp (°C)	Max Temp (°C)	Min Humidity (%RH)	Max Humidity (%RH)
7310005629	1. Portland, Maine	-12.8	50.8	0	97.8
7310005644	2. Anchorage, Alaska	-13.8	47.6	0	100
7310005628	3. Naples, Florida	-11.6	51.3	0	100
7310005627	4. Tempe Arizona	-15.3	41.9	3.2	100

The Shipping Study demonstrated that there is no adverse effect on hair samples that would affect the screening assay when samples are exposed to extreme temperatures and variations in humidity that might occur during sample transport. The average mean % of change in screening result prior to shipping and after shipping was 1.9% for all locations combined. Four samples out of 260 had screening results that were different prior to and after shipping. All of these samples were within $\pm 50\%$ (150-450 pg/mg) of the cutoff level where variances in a qualitative screening assay are to be expected.

COSMETIC TREATMENT:

Numerous studies have demonstrated that the use of cosmetic treatments can reduce the amount of drugs and metabolites detected in hair specimens. This effect is completely dependent upon the nature of the hair specimen and the treatment used, and is independent of the method of analysis. This study demonstrates that the Omega Laboratories, Inc. ELISA Opiates Screening Protocol is not an exception to this phenomenon.

Test conditions:

- BLEACH #1 - Salon Care Blue Flash Professional Powder Lightener
BLEACH #2 - L'Oréal Super Oreal Blanc® Professional Powder Bleach
- PERM #1 - Naturelle Natural Curls Alkaline Perm
PERM #2 - Natural Apple Self-Timing Perm
- DYE #1 - Revlon® Colorsilk™ Black
DYE #2 - Garnier Herbashine Soft Mahogany Dark Brown
- RELAXER #1 - Silk Elements™ No-Lye Sensitive Scalp Relaxer System
RELAXER #2 - Ultra Precise No-Lye Conditioning Relaxer
- SHAMPOO #1 - After Burner drug removing shampoo
SHAMPOO #2 - Ultra Cleanse drug removing shampoo

176 hair samples were used in this study. Of the 176 hair specimens, 112 specimens were identified as positive in the untreated Run No. 1 for opiates and/or oxycodone by ELISA assays and 64 specimens were identified as negative by ELISA assay. The ethnic origin, hair color and curvature were documented.

Each specimen was divided into 2 aliquots. One aliquot was analyzed by the ELISA protocol and the GC/MS confirmation method

The second aliquots were randomly assigned to the hair treatments listed above and the treatments were performed following the product insert.

Treated aliquots were analyzed by the ELISA protocol as summarized and the GC/MS confirmation method.

Table 8: Changes in ELISA Assay Test Results after Cosmetic Treatment
(Pos \Rightarrow Neg or Neg \Rightarrow Pos)

Treatment	Opiates	Oxycodone/ Hydrocodone	Comment
Bleach	None	None	NA
Dye	Pos \Rightarrow Neg (57) Neg \Rightarrow Pos (110)	None	Change at cutoff
Permanent	Neg \Rightarrow Pos (29)*	None	Change due to cross reactivity

Table 8: Changes in ELISA Assay Test Results after Cosmetic Treatment
(Pos ⇒ Neg or Neg ⇒ Pos)

Treatment	Opiates	Oxycodone/ Hydrocodone	Comment
Relaxer	None	None	NA
Shampoo	None	Pos⇒Neg (89) Pos⇒Neg (65)	Change at cutoff

*Cross-reactive at 0.24 for HDC to Opiates

There was no single treatment that had a more defined effect on the assay. The single largest change was observed in the relaxer for oxycodone at -34.8%. Bleach treatment appeared to have the consistent result across all drugs. All of the treatment appeared to have the greatest change on oxycodone. See Table 9 for summary of treatment percent change review.

Table 9: Summary GC/MS data for Cosmetic Studies

Treatment	Opiates Mean change in concentration (pg/mg)	OXY Mean change in concentration (pg/mg)	HCD Mean change in concentration (pg/mg)
Bleach	-10.4%	-15%	-10%
Permanent	-7.5	-14.5	-13.6
Dyeing	-7.5%	-18.3%	-15.6%
Relaxer	-2%	--34.8%	-7%
Shampoo	-1.4%	-17.8%	-3.4%

ENVIRONMENTAL CONTAMINATION:

Two studies were performed to investigate whether confirmatory testing procedures are able to distinguish between true analytically positive samples and those that have been externally exposed to Opiates, Oxycodone and Hydrocodone. The focus of the studies was to demonstrate that a methanol wash procedure mitigates the risk of false positive results while maintaining true analytical positive results.

The first study involved exposing drug-free hair to Opiates, Oxycodone and Hydrocodone, washing the hair with methanol three times, performing confirmation testing on the samples and the washes, and observing the final test result. The second study involved performing confirmation testing on known positive samples and observing whether the methanol washes change the final result. Head hair was used for this study.

Evaluating potential environmental contamination and the effectiveness of a methanol wash using this study design, all analytically negative samples tested remained negative after being subjected to Opiates, Oxycodone and Hydrocodone by the exposure modes described followed by a single methanol wash.

Additionally, all clinically positive samples tested remain positive after the wash steps were performed.

SUMMARY CONCLUSION:

The comparison of results of the proposed assay with the confirmatory GC/MS testing of head and body hair samples showed the results to be substantially equivalent

The candidate Omega Hair Drug Screening Assay for Opiates, Oxycodone and Hydrocodone (head and body hair) is substantially equivalent to the predicate Omega Hair Drug Screening Assay for Opiates, Oxycodone and Hydrocodone (k103161 for head hair) based on the design and performance studies discussed in this summary. Supporting Performance Testing presented for review in this document, includes agreement, precision, specificity, interference (including cosmetic effects), removal of environmental contamination, stability and shipping tests.